DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

Kimberly-Clark Health Care
Marsha Johnson, RAC, CBA
Associate Director, Regulatory Affairs
1400 Holcomb Bridge Road
Roswell, GA 30076

Re: K141612
Trade/Device Name: KIMGUARD® ONE-STEP® Sterilization Wrap
(Models: KC300, KC400, KC500, and KC600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 11, 2014
Received: July 14, 2014

Dear Mrs. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix B – Revised Indications For Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*

K141612

Device Name

KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC300, KC400, KC500, and KC600)

Indications for Use *(Describe)*

KIMGUARD* ONE-STEP* Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:
Advanced Sterilization Products STERRAD® Sterilization Systems that include:
STERRAD® 50, 100S, and 200
STERRAD® NX® [Standard Cycle, Advanced Cycle]
STERRAD® 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]

KIMGUARD* ONE-STEP* Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle and Advanced Cycle] and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]).

The KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC300, KC400, K500, KC600) have been validated for use with the STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX® and STERRAD® 100NX® cycles in Table 1.

KIMGUARD* ONE-STEP* Sterilization Wrap Recommendations for Use with the Advanced Sterilization Products STERRAD® Sterilization Systems are provided in Table 2.

TABLE 1: Validated Advanced Sterilization Products (ASP) STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX®, and STERRAD® 100NX® Cycles

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 50	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® 100S	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® 200	Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.
STERRAD® NX® Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. OR ONE single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.

TABLE 1: Validated Advanced Sterilization Products (ASP) STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX®, and STERRAD® 100NX® Cycles (Cont.)	
STERRAD® 100NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, ONE per tray per sterilization cycle.)
STERRAD® 100NX® Flex Cycle	ONE or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, ONE per tray per sterilization cycle).
STERRAD® 100NX® EXPRESS Cycle	Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.
STERRAD® 100NX® DUO Cycle	ONE or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter. • Flexible endoscopes without lumens

TABLE 2: Recommended Loads for KIMGUARD* ONE-STEP* Sterilization Wrap for use with Advanced Sterilization Products (ASP) STERRAD® Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle, Advanced Cycle], and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle])

KIMGUARD® ONE-STEP® Sterilization Wrap Models	Intended Load[1]	Weights of Wrapped Package Content Used in Validation Study (Total weight including tray)	Descriptions of Loads Used in Sterility Maintenance Validation Study
KC300	Light to moderate weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC400	Moderate to heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC500	Heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC600	Very heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments

[1]Intended loads include: Medical Instruments with and without lumens that include telescopes, endoscopes, cameras, light cords, and general use medical instruments

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
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Appendix A - 510(K) SUMMARY (REVISED)

Applicant's Name, Address, Telephone, FAX, Contact Person

Kimberly-Clark Health Care
1400 Holcomb Bridge Road
Roswell, GA 30076-2190,
USA
Contact Name: Marcia Johnson, RAC, CBA
Associate Director, Regulatory Affairs
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Fax: 920.380.6351
email: marcia.johnson@kcc.com

Establishment Registration Number: 1033422

Date: July 11, 2014

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification: Class II per 21 CFR 880.6850
Classification Name: Sterilization Wrap
Common/Usual Name: Sterilization Wrap
Product Code: FRG
Proprietary Name: KIMGUARD® ONE-STEP® Sterilization Wrap (Models: KC300, KC400, KC500, and KC600)

2. PREDICATE DEVICES

KIMGUARD® ONE-STEP® Sterilization Wrap, which is currently manufactured and distributed by Kimberly-Clark Corporation [510(k) Notification K113806, cleared August 20, 2013]

3. INDICATIONS FOR USE

KIMGUARD* ONE-STEP* Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- Advanced Sterilization Products STERRAD® Sterilization Systems that include:
  - STERRAD® 50, 100S, and 200
  - STERRAD® NX® [Standard Cycle, Advanced Cycle]
  - STERRAD® 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]

KIMGUARD* ONE-STEP* Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle and Advanced Cycle] and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]).

These models of the KIMGUARD* ONE-STEP* Sterilization Wrap have been validated for use with the STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX® and STERRAD® 100NX® cycles in Table 1 below.

***TABLE 1: Validated Advanced Sterilization Products (ASP)* STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX®, and STERRAD® 100NX® Cycles**

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 50	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® 100S	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 200	Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.
STERRAD® NX® Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. OR ONE single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.
STERRAD® 100NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, ONE per tray per sterilization cycle.)
STERRAD® 100NX® Flex Cycle	ONE or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, ONE per tray per sterilization cycle).
STERRAD® 100NX® EXPRESS Cycle	Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.
STERRAD® 100NX® DUO Cycle	ONE or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens

KIMGUARD* ONE-STEP* Sterilization Wrap Recommendations for Use with the Advanced Sterilization Products STERRAD® Sterilization Systems are provided in TABLE 2.

***TABLE 2: Recommended Loads for KIMGUARD* ONE-STEP* Sterilization Wrap for use with Advanced Sterilization Products (ASP) STERRAD®* **Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle, Advanced Cycle], and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle])**

KIMGUARD® ONE-STEP® Sterilization Wrap Models	**Intended Load[1]**	**Weights of Wrapped Package Content Used in Validation Study (Total weight including tray)**	**Descriptions of Loads Used in Sterility Maintenance Validation Study**
KC300	Light to moderate weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC400	Moderate to heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC500	Heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
KC600	Very heavy weight package (e.g., general use medical instruments)	10.7 lbs	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments

[1]Intended loads include: Medical Instruments with and without lumens that include telescopes, endoscopes, cameras, light cords, and general use medical instruments

4. DESCRIPTION OF DEVICE

KIMGUARD® ONE-STEP® Sterilization Wrap is comprised of two sheets of KIMGUARD® Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The wrap fabric is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight titanium dioxide pigment, and less than 0.008% by weight of a potassium phosphate anti-static treatment. The wrap allows a sterilized package to be opened aseptically.

Table 3: Device Comparison Table - Technological Characteristics

Technological Characteristics	Proposed: KIMGUARD® ONE-STEP® Sterilization Wrap	Predicate Device: KIMGUARD® ONE-STEP® Sterilization Wrap (K113806)
Manufacturer	Kimberly-Clark Corporation	Kimberly Clark Corporation
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG
Device Design	Two sheets of medium blue nonwoven polypropylene fabric. Each sheet of fabric is composed of three thermally-bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond polypropylene layers (SMS)	Two sheets of medium blue nonwoven polypropylene fabric. Each sheet of fabric is composed of three thermally-bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond polypropylene layers (SMS)
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments
Over the Counter Use Device	Yes	Yes
Single Use Device	Yes	Yes
(Continued on next page)		

Technological Characteristics	Proposed: KIMGUARD® ONE-STEP® Sterilization Wrap	Predicate Device: KIMGUARD® ONE-STEP® Sterilization Wrap (K113806)
Indications for Use	KIMGUARD* ONE-STEP* Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using: Advanced Sterilization Products STERRAD® Sterilization Systems that include: STERRAD® 50, 100S, and 200 STERRAD® NX® [Standard Cycle, Advanced Cycle] STERRAD® 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle] KIMGUARD* ONE-STEP* Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used. Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle and Advanced Cycle] and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]).	KIMGUARD* ONE-STEP* Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using: Advanced Sterilization Products STERRAD® Sterilization Systems that include: STERRAD® 50, 100S, and 200 STERRAD® NX® [Standard Cycle, Advanced Cycle] STERRAD® 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle] KIMGUARD* ONE-STEP* Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used. Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 50, 100S, 200, NX® [Standard Cycle and Advanced Cycle] and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]).
Maintenance of Package Sterility	Passed 180-Day Maintenance of Package Integrity	Passed 30-Day Maintenance of Package Integrity

5. SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to show that the KIMGUARD® ONE-STEP® Sterilization Wrap maintains sterility until used, after completion of the sterilization process in the STERRAD® Sterilization Systems.

Table 4: Sterilization Wrap Performance Tests

Study	Results
Maintenance of 180-Day Package Integrity	Passed

6. OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD® ONE-STEP® Sterilization Wrap performs as intended as a sterilization packaging system of medical devices when terminally sterilized in the STERRAD® Sterilization Systems. These studies show that the KIMGUARD® ONE-STEP® Sterilization Wrap met the same criteria as the predicate device and are substantially equivalent.